UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION
- - -

ETHICON ENDO-SURGERY, INC.,	: CIVIL NO. 1:07-CV-834
Plaintiff,	: Day 2 of Jury Trial Morning Session, Part 1
-vs-	: Opening Statements
HOLOGIC, INC., et al.,	: Tuesday, February 2, 2010 8:52 a.m.
Defendants.	: Cincinnati, Ohio

- - -

TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE MICHAEL R. BARRETT
AND JURY
- - -

For the Plaintiff: Sandra S. Bresnick, Esq.
Sidley Austin, LLP
787 Seventh Avenue
New York, New York 10019

Paul J. Zegger, Esq.
David A. Steffes, Esq.
Peter S. Choi, Esq.
Sidley Austin, LLP
1501 K Street, N.W.
Washington, D.C. 20005

Michael J. Timmons, Esq.
One Johnson & Johnson Plaza
WHQ-4122
New Brunswick, New Jersey

David E. Schmit, Esq.
Frost Brown Todd, LLC
2200 PNC Center
201 East Fifth Street
Cincinnati, Ohio 45202

For the Defendants: Robert J. Gunther, Jr., Esq.
Wilmer Hale
399 Park Avenue
New York, New York 10022

Proceedings recorded in stenotype.
Transcript produced using computer-aided transcription.

	Lisa J. Pirozzolo, Esq. Patrick M. Callahan, Esq. Wilmer Hale 60 State Street Boston, Massachusetts 02109
	James E. Burke, Esq. Keating Muething & Klekamp One East Fourth Street, Suite 1400 Cincinnati, Ohio 45202
Also Present:	Mark Casey, Esq. Verne Kreger, Esq. Lindsay McGinnis, Esq.
Law Clerk:	Stephanie K. Bowman, Esq.
Courtroom Deputy:	Barbara A. Crum
Court Reporter:	Julie A. Wolfer, RDR, CRR

- - -

PROCEEDINGS

(In open court at 8:52 a.m. Jury not present.)

THE COURT: Hey, on the depositions last night you guys only gave me three folders. I forget the witnesses' names. Is that what you wanted to give me?

MR. ZEGGER: That's right, Your Honor. I think we have more, more coming, but those are the full designations.

THE COURT: We'll have those -- Stephanie will give the rulings to you in a little bit.

You guys have things we can talk about before we bring the jury out?

MR. GUNTHER: One. One thing.

THE COURT: Okay. Let's just do it.

Are you ready, Julie?

Let's do it.

MR. GUNTHER: Your Honor, we have it's slide 16, and I gave it to Barb.

COURTROOM DEPUTY: I gave it to Stephanie.

THE COURT: Barb gave it to Stephanie.

MR. GUNTHER: Hey, Barb, I wasn't blaming you on that.

THE COURT: Do I need to see it?

MR. GUNTHER: I think you need to see it.

THE COURT: Okay. Give us a second. I got to go that way. I'll be right back.

(Recess in proceedings at 8:54 a.m.)

AFTER RECESS

(In open court at 9:01 a.m. Jury not present.)

THE COURT: I think we're still one juror short, guys.

MR. GUNTHER: Thank you, Your Honor.

THE COURT: You got the exhibit list just a moment ago?

MR. GUNTHER: Yes, sir, thank you.

THE COURT: Now, here's the deal: The ones that are overruled but I've got subject to the motions and subject to relevance, those are documents that you guys got from Ethicon so I don't think there's really a foundation problem.

MR. GUNTHER: Right.

THE COURT: But a lot of that stuff talks about the comparisons of products and things like that that I didn't think either side really wanted to get into, but, you know, so we'll play it by ear depending on what happens.

MR. GUNTHER: Okay.

THE COURT: It may come in or it may not come in.

MR. GUNTHER: Fair enough.

THE COURT: So what's -- this is --

MR. GUNTHER: This is slide 16. And basically what you can see on there is it's --

THE COURT: I can't see anything.

MR. GUNTHER: But here's what I think is trying to be depicted on this slide is that you've got the face page of four

articles from medical journals.

THE COURT: Yeah.

MR. GUNTHER: And then I think that there is going to be -- and I think these articles are all articles that they plan to use with Dr. Parker in his direct examination.

THE COURT: Okay.

MR. GUNTHER: And our position with respect to these articles is that they are hearsay. And the way that we understand the rule of -- the 703 rule is that while an expert can rely on hearsay, the expert can't -- that's not a vehicle to shovel the hearsay into in before the jury. So that, for example, if Dr. Parker wants to say that I've relied on a number of different articles, and I think it's probably appropriate for him to even mention what the articles are, but I think beyond that, the articles certainly do not go into evidence and the hearsay doesn't go in front of the jury.

So I think that, you know, this slide is now in the opening, right, so they're putting these -- obviously, the jury is not going to be able to read the articles but they're basically being told there's a bunch of articles we're going to show you and here's some quotes from them over on the left-hand side; and then when they get to Dr. Parker, they've got -- they've probably got a dozen slides, Your Honor, that are blowups of various articles that they want to just basically kind of now have him talk about and read -- and read to the

jury, and I don't think that's appropriate. I think he can rely on hearsay but the hearsay doesn't come in.

THE COURT: Who is going to handle that? Sandi?

MS. BRESNICK: Your Honor, can you hear me from here?

THE COURT: Sure.

MS. PIROZZOLO: Perfect.

Two things. Number one, the articles are not hearsay because they're representative of the state of the art. Much like the patents that we've objected to but defendants want to rely on, technically they're hearsay too but they're also representative of the state of the art.

THE COURT: What do they talk about, though?

MS. BRESNICK: The patents --

THE COURT: The articles.

MS. BRESNICK: The articles --

THE COURT: Yeah.

MS. BRESNICK: -- talk about the state of the art studies that have been done basically reflecting the thinking of the medical field at the time with respect to each of the different options for breast biopsy. And this is relevant because it goes to what was motivating a person of ordinary skill in the art at the time and what doctors were looking for, what were the needs and what were the medical needs that were not being met, and these articles help to demonstrate that.

MR. GUNTHER: Your Honor, they're not being offered as

prior art, and I think --

THE COURT: Well, I don't know what they're being offered as. So here's the deal: She can use these in her opening statement, but when you attempt to use them with the witness, you'll renew your objection and we'll see if the witness can get around where they're going to go.

MR. GUNTHER: So it may be a situation where if Sandi -- if Ms. Bresnick uses it in her opening, and her witness may not be able to use these.

THE COURT: Yeah, exactly.

MR. GUNTHER: So she's got to make that decision.

THE COURT: Yeah.

MR. GUNTHER: Understood, Your Honor.

THE COURT: Yeah. So just bring it back. I mean, it's, you know, I don't know what the articles say exactly. I'm not sure where you guys are going with them. So we'll just have to see how it pops up and if it gets in.

You might be able to close the loop on that, Sandi, you might not.

MR. GUNTHER: Thank you, Your Honor.

MS. BRESNICK: Thank you, Your Honor.

THE COURT: Okay.

MR. GUNTHER: Now, Your Honor, we do have some additional objections to Dr. Parker. I understood that we were going to try to handle those at a break.

THE COURT: Well, here's the deal: I in general overruled your motion regarding the Daubert. Let's see how he gets qualified. It's up to you if you want to voir dire him after she does her qualifications or if you just want to wait and use it in cross and see what he does. So, I mean, the additional objections I assume are going to his foundation; right?

MR. GUNTHER: Some of them go to foundation. Some of them go to -- a number of them are ones that go to sort of the hearsay issue of the documents. I can do them as they come up.

THE COURT: Yeah, let's do it that way.

MR. GUNTHER: I'll do that. That's fine.

THE COURT: Yeah.

MR. GUNTHER: Your Honor, they have told us that the issue, the sort of the Daubert issue is really not -- and I know you've made a ruling on that, but it's not going to come up today because he is not going to talk about the prior art or any validity issues. My understanding counsel for Ethicon has told us that they're going to basically put him on for various things that don't relate to validity now and they're going to bring him back in their rebuttal case to talk about validity. So --

THE COURT: Okay.

MR. GUNTHER: -- I just wanted to let you know kind of what the state of play is.

MS. BRESNICK: And, Your Honor, we will go through a little bit of the background for that for next week so there's some context, but we do not intend to go into any of the response or rebuttal to what the prior art is because, quite frankly, we don't know what prior art the defendants are going to rely on at this time.

THE COURT: Okay. What's the status, Barb?

COURTROOM DEPUTY: We're ready to go.

THE COURT: We're ready to go. Are you guys ready?

MR. GUNTHER: We're ready, Your Honor.

THE COURT: Okay. And you guys will -- did you reach an agreement on the separation issue?

MR. GUNTHER: Your Honor, here's -- here's where we are.

THE COURT: Fine.

MR. GUNTHER: Corporate -- each side can have a corporate representative in the courtroom for all purposes.

THE COURT: Yeah.

MR. GUNTHER: Right.

THE COURT: Thank you.

MR. GUNTHER: And in fact duh. I'll start up with the obvious.

THE COURT: Good. You agree.

And they can have their lawyers in the room too. Yeah, that's right.

MR. GUNTHER: Yeah, all right.

And then in terms of experts, we've agreed that experts can be in for everything.

THE COURT: Can watch the whole trial.

MR. GUNTHER: Yes.

THE COURT: Okay.

MR. GUNTHER: And then fact witnesses are sequestered during testimony.

THE COURT: Okay.

MS. BRESNICK: Corporate reps -- I didn't hear if you mentioned corporate representatives can be here.

MR. GUNTHER: For all purposes.

THE COURT: Yeah, sure.

MR. GUNTHER: That was the one that the Judge basically said "duh" about.

THE COURT: I'll be saying that a lot in the next couple weeks.

MR. GUNTHER: Your Honor, you're going to be saying it a lot to me.

THE COURT: For different reasons, though.

Set?

Did they -- they've got their notepads?

COURTROOM DEPUTY: Yes.

THE COURT: And are they going to use tear-off sheets?

COURTROOM DEPUTY: Yes.

THE COURT: Can you remind me of that at the end of each witness so I don't forget?

COURTROOM DEPUTY: Yes.

(Jury in at 9:08 a.m.)

THE COURT: Okay. Everybody good to go?

A JUROR: Yes, sir.

THE COURT: Anybody go on the internet last night and blog anybody on this? I hope not.

Okay. We're about to have the opening statements, and as I mentioned yesterday in the preliminary instruction, the opening statements are not evidence but what they are is it's a discussion between the lawyers and you of what they think the evidence is going to show. Okay.

All right. Counsel.

MS. BRESNICK: Thank you, Your Honor.

Good morning, ladies and gentlemen. Allow me to reintroduce myself. My name is Sandi Bresnick, and I am honored to represent Ethicon Endo-Surgery. We are looking forward to showing you our case.

We will be showing you three main points throughout our presentation. They are the United States Patent Office granted my client, Ethicon Endo-Surgery, three patents covering breast biopsy technology. This breast biopsy technology saves lives. The third point, defendants Suros and Hologic infringed these patents and because of that, Ethicon should be

compensated for their infringement.

Let's step back a moment. Who is Ethicon Endo-Surgery? Ethicon is a Johnson & Johnson company. The breast care division is headquartered here in Blue Ash. They have patents covering breast biopsy technology.

Breast cancer, I'm sure you're all aware, is a very serious disease. The statistics are compelling. One in eight women will be affected by breast cancer in her lifetime. So that means statistically everyone in this room today knows someone who's had breast cancer, a friend or a relative. It's the second leading cause of cancer deaths among women.

It goes without saying that the sooner you can detect the cancer, the better a woman's chances of survival, the better treatment options there are, the better chances of survival. Early detection is absolutely critical.

So how do you get to this early detection? Well, breast biopsy is one -- is the way that doctors would do it. Breast biopsy is taking a sample of a suspicious mass or a lesion, something that the doctor finds, either you could feel it yourself, you can look on an x-ray, maybe you'll see it on ultrasound, but doctors will screen women or women will examine themselves, they will find a suspicious mass, and maybe the doctor will want to take a sample of that mass to see does this have cancer or not.

So before Ethicon's breast biopsy technology, how were

doctors looking at doing breast biopsies? What were the options available? Well, today you will meet Dr. Steve Parker, one of the world's leading experts in the field of breast biopsy and breast disease, and he will explain what doctors had available to them at the time. What's the date we're talking about? We're talking about 1994. And Dr. Parker will explain there were only three options.

The first was open surgery. I'm about to put up on the slide a picture which is graphic so I wanted to warn you, but I think it's important for you to understand what was involved. Now, open surgery, as you might imagine from the name, requires hospital stay, general anesthesia, going under the knife. The doctor would -- and here is the picture (indicating) -- open the woman's breast and remove -- remove a hunk of tissue.

Now, this was the gold standard of breast biopsy care from about the 1960s to the 1990s, but this method certainly had some drawbacks. First one, of course, is that it was invasive. There were risks for general anesthesia, risk of bleeding, infection, stroke, and death. The woman after the tissue was removed and if she healed would often be disfigured, the breast would not be the same shape and size as the other breast. Obviously, there were hospital stays and recovery that were involved. And after all of that, there was still the opportunity that the doctors would miss the cancer. And we're

going to show you why open surgery missed cancers and even though this was the gold standard from about the '60s to 1990, this was the best that medicine had to offer.

Well, there was another option that was available. We'll show you that. It was called fine needle aspiration. Now, this wasn't an open or invasive procedure. Here a very fine needle would be inserted into the lesion and cells would be withdrawn. But there was simply not enough sample for the doctor to accurately tell if the woman had cancer or not. We will explain that this procedure, FNA, missed too many cancers. What was the result of that? The woman was told that she didn't have cancer when in fact she did. So that would delay her ultimate diagnosis of cancer. It would decrease her chances of survival. It would reduce the number of treatment options that she had available.

There was a third option, it was called core needle, but this had serious drawbacks too. We will explain and we will show you that core needle cannot be reliably used in certain types of breast tissue. You couldn't get a sample, you couldn't get an accurate sample. Even in the best of cases, we will show that core needle could only take one sample at a time which is what we've depicted here (indicating). If this is your suspicious mass, you're only taking one sample at a time; and each time you take a sample, you have to reinsert the needle into the breast. Multiple samples, multiple insertions

were required, and often you would miss the target altogether. And we'll explain how that happens even when the device was properly used by qualified doctors. So this option also led to missed cancers.

So as of 1994, this was the best that we had, open surgery, fine needle aspiration, and core needle. That was the best that medical science had to offer, but clearly this wasn't good enough.

So what happened next? There were a group of doctors and engineers at a company called Biopsys who set out to try to change the standard of care, and we will show how they invented technology that solved the problems that we just mentioned. What was the new technology? Well, you'll meet Dr. Parker and he will explain how he worked with the engineers to help them design and develop new technology and we will describe how it all came about.

What was this new technology? Vacuum-assisted breast biopsy. We will explain that this is a -- unlike open surgery which is an invasive procedure, this is a minimally invasive procedure which means that the doctor could go in, just a little tiny nick in the skin, insert a needle, and get out all of the tissue that he needed with one insertion of the needle.

How did this work? It used vacuum to pull the target tissue into an opening of the needle and acquire all of the tissue that it needed. We'll explain how all of this works.

Basically you had a, as I mentioned, single insertion of the needle. You had a rotating and translating cutter, meaning a cutter that moved back and forth within the needle, that would cut the tissue pulled into the aperture of the needle. The vacuum would then pull the tissue back, the doctor could then in a real-time fashion obtain the tissue and send it to pathology. This technology saved lives and changed the standard of care for breast biopsy and we will show you how.

The technology that the Biopsys inventors came up with impressed my client, Ethicon Endo-Surgery, so much that they bought the company. Ethicon Endo-Surgery bought Biopsys, bought the patents and applications, and it even bought the product that Biopsys had created using the very technology.

Let's take a look at one of the patents that Ethicon Endo-Surgery purchased. This is Ethicon Endo-Surgery's U.S. Patent Number 7,226,424, and after our opening statements we'll hand you out a copy of the '424 patent, but you'll see here you've got the number of the patent here in the top right-hand corner (indicating). For ease of convenience, we're going to abbreviate this as the '424 patent. We'll just take the last three digits off of this number and we'll call it the '424 patent. But you'll see that the '424 patent was filed or a parent application of the '424 patent was filed in 1994. These are the individuals who invented the technology that's in this patent: Mark Ritchart, Mike Stuart, Fred Burbank, Kenneth

Galt. And you'll see here who is the owner of that patent. It says Ethicon Endo-Surgery.

This is a picture of the first vacuum-assist breast biopsy device (indicating). This device, we will show, uses the technology of the '424 patent. And Dr. Parker will explain how this device worked. Again, this was launched in 1994, the same time that the parent application to the '424 patent was filed in the Patent Office. We will explain how this device and VAB technology, vacuum-assist breast biopsy technology, became a standard of care for certain types of breast lesions.

Now, as good as this technology was, and it was good, it didn't solve all the problems. What was the problem? This Biopsys Mammotome was not designed for use in ultrasound. As some of you may be familiar with ultrasound, you've probably seen it, it's a way to look into the body real time, you've seen it typically used to monitor the progress of a baby in a pregnant woman. It involves a wand that's applied over the area to be visualized, and the doctor can see three-dimensionally inside the body real time. It's a device that doctors use to see inside the body. Ultrasound can also be used to look at breast tissue.

This device could not be used effectively in breast tissue, and we will explain why that is so. This device was only used in a procedure that involved X-ray. So the woman would be on an X-ray table with her breast basically through a

hole in the table between compression plates. An X-ray would be taken to pinpoint where the lesion was, and then this device would be positioned where the lesion was and then the samples would be taken.

Ultrasound -- so let me just step back for one second. So this device using X-ray basically gives a doctor a two-dimensional picture of where they want to target the lesion.

Ultrasound is a real-time, three-dimensional picture. It's kind of like the difference between a still photograph and a movie and IMAX. This device could not be used with a movie and IMAX type imaging situation, so things had to be done.

So what happened? Well, by this time it's 1997. Ethicon Endo-Surgery has already bought Biopsys and they started out on the task. They started what was called Project Gateway. This was a big project for the company at the time. It took -- they devoted over twelve engineers to the product -- project, spent over nine million dollars in research and development, and it took over two years to complete. And you'll meet some of the engineers who worked on Project Gateway.

What were some of the results of Project Gateway? Well, two patents were some of the results of Project Gateway. You'll have these patents in your notebook as well. And, again, you'll see the patent number in the right-hand corner. You'll see on the first page the inventors of the patents,

including Mr. John Hibner and Mr. Jon Buzzard, both of whom you'll meet. The '487 patent was filed in 1999. The '768 patent, a parent of that patent, was filed in 1999.

What else came out of the Project Gateway? Well, out of the technology that the inventors developed, they also came up with a commercial device, and this is it (indicating). This was the Mammotome HH or hand-held. It was launched in 1999. This was the first ever hand-held vacuum-assist breast biopsy device that could be used in an ultrasound environment, and we'll show here this is the device (indicating). This is the handpiece, and a doctor could use this hand -- use this device with a single hand and maneuver and manipulate it while he was using the ultrasound transducer at the same time. The device could take samples and respond -- and the doctor could respond real time to what the information was that he was getting from the ultrasound transducer. The old Mammotome product couldn't do that. This system did it. And as I said, two years of research and development, over nine million dollars, and over twelve engineers.

We'll show you how this device was used by doctors. We will also show you that this vacuum-assist breast biopsy technology, starting from the Biopsys Mammotome going through the Biopsys -- the Mammotome HH and subsequent iterations, the vacuum-assist breast biopsy technology that's Ethicon's became the standard of care for many types of lesions. We will show

that the Mammotomes have been accepted by doctors. More than three million biopsies have been performed using Mammotomes.

So to recap, Ethicon Endo-Surgery has patents. The patented technology saves lives. So why are we here? We are here because defendants Suros and Hologic infringed these patents. We will show that the defendants make an infringing product system called the ATEC. There's an example of it here (indicating). That infringes Ethicon Endo-Surgery patents. We will show that the ATEC products infringe claim 10 of the '487 patent. We will show that the ATEC products infringe claims 1, 2, and 7 through 9 of the '768 patent. And we will show that the ATEC products infringe claims 2, 5, and 9 of the '424 patent.

You may recall yesterday during -- during instructions the Judge indicated to you that we have the burden, Ethicon Endo-Surgery has the burden to show infringement by the preponderance of the evidence, and the Judge will instruct you on the law again at the end of the trial. Preponderance of the evidence is merely the greater weight of the evidence. If the evidence is equal, in other words, if you've got two reams of paper on the scales of justice, then we haven't met our burden. However, if there's slightly more evidence in our favor, then we've carried our burden of proof. We submit that we are going to show you more than just a little bit of evidence to show that, that the ATEC products infringe, but all that's required

is the scales be slightly tipped in our favor.

So let's look up close at what these devices are. Up top is the handpiece, and I've -- we've cut off here (indicating), these are tube and vacuum lines. We took those off so that you could have a clear picture of what the handpiece looked like, but you'll see what an actual handpiece looks like. We've got one here. This is it (indicating). We just didn't depict all of these tubes. These tubes have several functions. One is vacuum that's going to pull the tissue through the handpiece into a tissue collection chamber (indicating) which is right here. And you'll see that. It's this piece here (indicating) on the screen.

So let's take a closer -- a little bit of a closer look at what you are going to be asked to do throughout the course of this trial. The first claim is claim 10 of the '487 patent. And you may remember from the tape yesterday, the video that we watched, that the claim of a patent is like a fence around your property. This tells everybody else in the world where your property begins and ends. Here's the claim, here's the fence or the electric fence around our property here. Claim 10, and you'll have it in your juror notebook, it will be at column 16, and at the bottom of column 16, lines 47 to 67.

So I've put a box around that claim. That's our electric fence. Now I'm going to show you all of the words

that -- in this claim that the defendants do not dispute.

Notice anything? It's all highlighted. The defendants do not dispute any of the words in the -- in claim 10 of the '487 patent. They do not dispute that the ATEC systems fall within that electric fence of claim 10. No dispute at all.

Let's take a look at the claims of the '768 patent. They are claims 1, 2, and 7 through 9. And I've put a box around them as well. Again, column 16 from lines 2 to 18 and column 16, lines 31 to 37. And I'm going to highlight here all of the words in these claims again that the defendants do not dispute.

Notice anything again? They don't dispute any of the words in those claims. They do not dispute that the ATEC systems fall within the electric fence of those claims. They don't dispute that the ATEC systems fall within the scope of claims 1, 2, and 7 through 9 of the '768 patent.

Let's look at the next patent. Claims 2, 5, and 9 of the '424 patent. And, again, I've put a box around these claims. Claim 2, when you get your patent you'll see is kind of hard to read on this screen, but claim 2 depends from claim 1. It says the method of claim 1 and then it adds another step. So all of the features of claim 1 are also included into claim 2. That's why I've drawn a box around claims 1 and 2, but we're only talking about claim 2, 5, and 7 through 9 of

this patent.

Now, again, I'm going to highlight the terms of the claims that they don't dispute in yellow and we'll see if there are any -- any quibbles with any of the language here.

Ah, okay. There are a few quibbles with the language here. I've highlighted those in blue. So the term "tissue sample holder" appears in claims 2 and 5 a couple of times. Pulled that out. And the term "tissue storage compartment" appears a couple of times in claim 9. So the dispute here whether the ATEC product falls within the scope of the electric fence of the '424 patent is going to turn on whether the ATEC has a tissue sample holder or a tissue storage compartment. We will show that the ATEC does indeed have a tissue sample holder or tissue storage compartment.

Now, the Court has already looked at the terms "tissue sample holder" and "tissue storage compartment" and defined those terms for us. These terms "tissue sample holder" and "tissue storage compartment" are, "for example, a container, a receptacle, cartridge, cassette, or other tissue sample holder that is suitable for housing tissue samples during collection and transportation for analysis."

Suitable for. Suitable for transportation. Actual transportation doesn't have to be shown. It just merely has to be capable of transporting tissue for analysis. Is the ATEC -- does the ATEC have a compartment that's suitable for

transporting for analysis? We think it does.

Now, let me show you the terms here that the defendants do not dispute. All the terms in yellow, they do not dispute the vast majority of the definition of "tissue sample holder" and "tissue storage compartment." They only have a quibble with one part of it, whether the tissue sample holder is suitable, capable for transportation for analysis. So that's what this dispute is all about. Is the ATEC, does it have a component that's suitable for transportation for analysis? We say it does.

So let's take a look at the handpiece. Again, this is the handpiece (indicating). You'll see these are vacuum lines and saline lines. During the procedure -- actually get a different -- this one is just a little less cumbersome. I've taken off the lines so I can show it (indicating). But vacuum -- this is the needle. The needle would be inserted into the breast. The vacuum is going to be applied. The needle has a notch at the front. It will open. The tissue will get sucked into the notch. A cutter inside the needle will rotate and translate back and forth across the aperture of the opening of the notch, suck the tissue down, and pull it back through the handpiece.

Now, where does that tissue go? It goes right here (indicating) into this part here. The fluid, saline that's being pumped into the system here, gets pulled out the back.

The doctor wants to take another sample, simply turns the handpiece to get the notch of the needle at a different part of the lesion, presses sample, the doctor -- the tissue gets sucked back into the notch; again, the cutter rotates and translates forward cutting the tissue. Vacuum pulls the tissue back through the handpiece into this part here (indicating). This is the part that collects all the tissue. This is the part that's the tissue sample holder or tissue storage compartment.

Now, when the doctor is done with the procedure, what does the doctor do? So at this point all the tissue that the doctor wants is here in this basket at the end of the device. The tissue has been -- we will show that the tissue has been bathed in saline; that the vacuum has been applied and pulled the tissue back to the end of the basket here. When the doctor is done, the doctor simply unhooks it like this (indicating). Let me show that again. The doctor is done, unhooks it like this (indicating), removes the -- this part from the handpiece. The tissue is in this basket here.

So what does the doctor do? At this point he transports the basket somewhere else for analysis. First place he might take it is to the benchtop. He might take the tissue out and look at it visually. Sometimes doctors, we will show you, sometimes doctors get visual information just by looking at the quality and the nature of the tissue that comes out.

And you'll notice that there is inside this basket a little scoop. That helps the doctor remove the tissue from within this container.

You may also notice (indicating) -- let's see. Back up.

This is why I used the prior one.

So, again, at the end of the procedure, doctor unscrews it from here (indicating), takes the basket out, and then he transports the basket somewhere else. The first step, the doctor might look at it visually. We will show that the doctor can do other things with this tissue basket. So in addition to taking this to the benchtop and taking the samples out and visually inspecting them, the doctor can do something else with them too. The doctor can take this basket and drop it into a jar of preservative. Why would the doctor do that? Well, if the doctor wants to send these to a pathologist to be analyzed, the doctor typically will put it in a jar of preservative. In this case it's typically formalin. Plop it right into the jar, screw the jar top on, and send it down the hall to pathology, or the doctor can simply just walk down the hall if the pathologist were right next door without putting it in the formalin. But the purpose of the formalin, we will show, is if the pathologist can't get to it right away, the tissue needs to be preserved or fixed in the formalin and then the pathologist can look at it later.

But the question is is this basket suitable for dropping in a jar of formalin so that it can be taken to a pathologist? We'll show you bet it is. You'll notice that this basket has -- is made of a tiny, very, very fine mesh. What's the purpose of the mesh? The purpose of the mesh, we'll show, is to keep the tissue inside but the mesh will also let in the formalin. So this will have -- this will end up being a convenient package of the tissue sample where the formalin can get in and fix the tissue. Perfectly suitable for transporting this tissue sample to a pathologist. We will show more than suitable, more than capable of transporting for analysis. It can be transported visually for inspection, it can be transported in a jar of formalin. We will show these things.

There is one final photo I wanted to show you. I mentioned visual inspection. This is a -- this is an example where the doctor has taken the tissue collection basket off of the back of the device as I mentioned and brought it over to a bench to visually inspect it. This document comes from the defendants' own files (indicating).

So does the ATEC have a tissue sample holder or tissue storage compartment? We will show that it does. The picture doesn't lie.

So why are we here? We are here because Hologic and Suros have infringed our patents, and we will show you that this infringement has caused Ethicon Endo-Surgery substantial

harm. Substantial harm. We're going to ask you for a big number at the end of this trial for the years of defendants' infringement. We are going to ask you for 92 million dollars, and we will show that that is how badly Hologic and Suros have hurt Ethicon Endo-Surgery.

Now I want to say a few words about validity. You remember the instruction from yesterday. Patents are presumed to be valid. Here they are. The Ethicon Endo-Surgery patents are presumed to be valid. The Patent Office is presumed to have done its job correctly, and because of that, it is the defendants that bear the burden of proof to show that the patents are invalid. And what's the burden of proof that they have? It's clear and convincing evidence. They must prove by clear and convincing evidence that the patents are invalid. Now, the Judge explains this -- explained this burden yesterday. It's not beyond a reasonable doubt, not the criminal standard, but it's the one just below that. It's beyond a substantial doubt. They must prove that the Patent Office, that the United States Patent Office made a mistake, not once, not twice, but three times, and we will -- it is our firm belief that they will not meet their burden of proof.

We think you're going to hear a lot of excuses from the defendants, a lot of could haves, would haves, should haves, a lot of excuses. But we will show that the United States Patent Office considered all of the relevant information

when it examined the patent applications and determined that the inventions were worthy of patents. We stand behind our three patents. We are proud of them. They cover important inventions that save lives.

Suros and Hologic infringed these three patents and they should compensate Ethicon Endo-Surgery. We look forward to presenting our case to you.

Thank you.

THE COURT: Thank you, Miss Bresnick.

Miss Pirozzolo, Mr. Gunther, who is going to handle this?

MS. PIROZZOLO: I will be, Your Honor.

Your Honor, ladies and gentlemen of the jury, my name is Lisa Pirozzolo, and with my colleague Bob Gunther who you met yesterday, I'll be representing Suros Surgical Systems, Inc. and Hologic. Also here today with me is Mr. Mark Casey who is the general counsel of Hologic.

I want to thank you for being here today and for helping us resolve this dispute with Ethicon and for giving Hologic and Suros their day in court. This is a very important case to Hologic and its 4,000 employees. This is also an important case, and I think Miss Bresnick and I can agree on this, because of the nature of the product at issue here, a device used to diagnose breast cancer.

The finest, most advanced breast biopsy device on the

market are ATEC, automated tissue excision and collection system. That's what we call the ATEC. Since coming on the market in January, 2002, the ATEC device has broken new ground. The ATEC device was the first ever minimally invasive breast biopsy device that could be used with MRI which is the best type of imaging technology to use in women at high risk of developing breast cancer.

Innovations in the ATEC have also made the device faster and less painful for women who are undergoing biopsy procedures. Since the ATEC was introduced to the market in January, 2002, more than 750,000 women have had procedures performed with an ATEC device.

Our position in this case is simple and can also be summarized in three points. Point number one: Joe Mark and Mike Miller who founded Suros and who are sitting here in the courtroom today -- Joe, could you stand up?

(Mr. Mark complied.)

MS. PIROZZOLO: And, Mike, could you stand up?

(Mr. Miller complied.)

MS. PIROZZOLO: -- invented the ATEC using core technology they developed and patented before any of the Ethicon patents in this case was ever filed.

Point number two: The Ethicon patents being asserted here are not inventive and cover minor improvements that are obvious in view of what people in the field of minimally

invasive tissue removal already knew at the time.

Point number three: Despite the fact that the ATEC device was introduced in January, 2002, Ethicon did not claim infringement of these patents until October of 2007 when it filed this lawsuit. The evidence will show that Ethicon filed this lawsuit because it could not compete in the marketplace against Hologic and Suros's superior technology.

This morning I would like to review with you the evidence we will present at trial on these three key points. The story of the ATEC really starts with the two men I just introduced you to, Joe Mark and Mike Miller, and you will have the opportunity to hear from them during the trial. In the mid 1970s when Joe Mark was a high school student growing up in Indianapolis, he had a keen interest in technology and in particular he loved tinkering around with stereo systems. Mike Miller was a engineer who worked at RCA and he volunteered to serve as a mentor to the local scouting troop. Joe Mark was one of those scouts, and the two met and hit it off because they really loved technology.

For several years the two went their separate ways. Joe Mark went on to college at Indiana -- in Indianapolis at Butler University. After college, he started working at a company called Davidson that sold air motors and in particular one of Joe's customers was someone who was using air motors in medical devices. A couple of years later, Joe got into the

medical device field himself and started selling devices that were used in eye surgery. These early experiences gave Joe Mark an opportunity to examine medical devices and talk to doctors who were using them, and what he found out was that doctors were very interested in minimally invasive tissue removal but they wanted better, faster devices and they also wanted devices that were easier on patients. These conversations gave Joe Mark the idea of developing his own minimally invasive tissue removal device, and that means a device that could obtain tissue by removing it by inserting a piercer in the skin through a needle rather than the open surgery of the sort Miss Bresnick put a picture up about.

So in 1987, Joe Mark called his old mentor Mike Miller and asked him if he would like to join him in starting a company to develop this type of technology. From the very start, the two men were guided by the principle of designing and making products that would meet the needs of doctors and evolutions in the medical field. Joe Mark's special talent is talking to doctors, figuring out what they need. Mike Miller with his years of engineering experience at RCA knew how to make these ideas really work.

The evidence will show that they made and still make a good team. They started by developing a basic platform system that could be used as needed for all different types of tissue removal. They called this platform and their first prototype

the MIS, which stands for minimally invasive surgery. And I'm going to put up a picture of this initial prototype.

The MIS had a lot of features that we're going to discuss throughout the trial. In particular, it had a console. It also had a handpiece designed to be used with a single hand. You can see the console has an electronic display here, and what that display would show was, this is small print, but that says "irrigation," so the saline going to the site of the tissue removal, and "aspiration" which refers to vacuum.

Here is a close-up picture of the handpiece (indicating). You can see the handpiece featured an outer piercer with a notch on the side, and we have a close-up so you can see the notch. And so you'd insert that into the place where you wanted to take tissue from.

Inside the piercer is a cutter. You can see that moves across the notch to cut tissue that is drawn into the opening. And what is used to draw it into -- draw tissue into the opening in this device was vacuum power.

Now, this type of outer piercer and inner tube as a cutter is called a tube in tube cutter. And this is -- was known in the field of tissue removal technology. The MIS device also used the vacuum to draw the tissue back once it was removed into a tissue container.

The evidence will show that this MIS prototype was the basis of all the tissue removal products that Joe Mark and Mike

Miller later designed, marketed, and sold, including the ATEC device that's being accused of infringement in this trial. Work on the MIS started in the late 1980s, and the prototype that I'm showing you here was developed in 1992. That is long before any of the Ethicon patents being asserted in this case was ever filed.

What came next for Joe Mark and Mike Miller? The MIS provided a basic platform for removing tissue, a minimally invasive tissue removal device. But what they wanted to do was develop their device for use in particular parts of the body. Their first focus was removal of tissue in the back. When you have a herniated disk, the tissue that sits between the vertebrae can get out of shape and press against nerves. Removing that tissue can relieve the pain. So the evidence will show Joe and Mike started working on a device to remove that tissue which they called a diskector. They sold their first diskector in 1993. That's more than a year before the first Ethicon patents in this case were ever filed. And I'm going to show you a copy -- a picture of the diskector that was developed by Joe Mark and Mike Miller.

As you can see (indicating), it has a console. It has a foot switch. It has a handpiece that can be held with a single hand. And you can see in this close-up that the console had a display with icons and also had control buttons.

I'm also going to show you a close-up of the handpiece

of the diskector. As you can see, the diskector has the same type of tube in tube cutter, the piercer with the notch in the side (indicating). It also used vacuum power to pull tissue into this notch and back into the tissue storage container. So this was all work done before the Ethicon patents in this case were filed.

Joe Mark also filed a patent on an apparatus for minimally invasive tissue removal. And if we take -- this patent was filed in February, 1993. Again, before the Ethicon patents in this case were filed. And if you take -- if we take a closer look at the patent, and in particular at the background of the invention, that's where the inventors get to explain their invention, you can see that they say, "The present invention relates to surgical methods and apparatus for the excision and removal of a wide range of tissues." They then go on to delineate a great number of different sorts of tissue procedures, neuro, spinal, orthopedic, ophthalmic, dental, gynecological, gastrointestinal, and it goes on and on with different procedures and ends with "as well as other areas of the body requiring great care in the removal of tissue." So you can see from the outset Joe Mark and Mike Miller were interested in applying minimally invasive tissue removal devices to all different parts of the body.

Now, here is the schematic of the invention in Joe Mark's patent. You can see the device consisted of a console,

that's highlighted in green; a foot switch, that's highlighted in orange; a handpiece designed to be used with a single hand; and a tissue -- a container for tissue which we have in blue (indicating). The summary of the invention described how this device worked. In particular, it says "a system for minimally invasive percutaneous tissue removal using a hand-held cutting tool."

The patent also described a tube in tube cutting device. The patent also described the use of aspiration or vacuum to draw tissue into the device. And it also included a description of an analog display to show pressures and speeds, the operation of the device.

This patent and other evidence we will present at trial will show that even back in the early 1990s before any of the Ethicon patents in this case was filed, Joe Mark and Mike Miller were thinking about ways to apply minimally invasive tissue removal to all different parts of the body.

Now, after the diskector, the back tissue removal device, they wanted to make a device that an ophthalmologist could use to remove eye tissue. They called that device a vitrectomy device, and just like the diskector and the MIS platform before it, the vitrectomy device had a console, a foot switch, a handpiece that could be used with a single hand. The handpiece had the same tube in tube cutter. It used vacuum power to draw tissue into the piercer and then pulled that

tissue back into a container. The vitrectomy device was first sold as a commercial product in 1997. Bausch & Lomb sells that device and it's been used in thousands of eye surgeries over the years.

Now, at this same time work was being done to develop the minimally invasive tissue removal platform. Joe Mark and Mike Miller were working on other types of tissue removal devices as well. In particular, they were working on making and selling what Miss Bresnick mentioned and what are called core needle biopsy devices, and these devices are used to obtain cores of tissue. And I have a picture of one here. This is one of the devices that Joe Mark and Mike Miller were involved with making and selling. These core needle devices are still being sold today and are commonly used to take breast biopsies and procedures where a doctor is using ultrasound, and Joe Mark and Mike Miller were selling this type of device for use in breast biopsies in 1994.

But they knew from their interactions with doctors who were using core needles that they wanted other options too. So the evidence will show that in the mid 1990s, Joe Mark and Mike Miller turned their attention to developing their basic MIS minimally invasive tissue removal platform to use it for breast biopsies. They did some initial prototype work in 1995 but they really started to concentrate their efforts in 1999. In 2000, they started Suros Surgical Systems, Inc. When they

started, they had three employees, but they worked hard and the result of that hard work was the ATEC device.

So how was the ATEC developed, this device that's being accused of infringement? Well, really it's the same old story. Joe Mark and Mike Miller took their basic MIS platform for minimally invasive tissue removal technology and adapted it to be suitable for use in breasts. This is the first version of the ATEC, and we have a real one right here (indicating). And as you can see, it had the same features. It had a console. It had a foot switch. It had a handpiece designed to be used with a single hand. These are the fundamental features that existed in the MIS platform that had been developed in 1992. The handpiece has the same tube in tube cutter and it -- the hand -- the device uses vacuum to draw tissue into the opening in the piercer and to pull it back into a tissue filter.

But the evidence will show that Joe Mark and Mike Miller did not stop with the technology they already developed. They continued to innovate. There was already one vacuum-assisted device on the market, the Mammotome, and the Mammotome was being sold by Ethicon, and they knew they had to do something different and better in order to compete with Ethicon in the marketplace.

To make their product better, the Suros founders did what they had always done. The evidence will show Joe Mark

went out and talked to doctors to find out what they were doing and what they needed while Mike Miller worked on developing the technology to realize those needs. The unmet needs were pretty obvious. Doctors wanted a device that was smaller, lighter, easier to maneuver. They wanted a device that was faster so that women could get through the procedure more quickly and with less anxiety. They wanted a device that minimized pain for patients.

Another thing they focused on was MRI compatibility. With minimally invasive surgical devices, doctors need a way to see the lesion that they're concerned about. Traditionally X-ray type devices had been used, ultrasound had been used, but MRI technology was becoming more available and Suros wanted to be in the forefront. The problem, though, is the M in MRI stands for magnetic. So electric motors which have magnets in them would not be compatible with MRI and would not be safe to use in an MRI suite. So to make a tissue removal device that was safe with MRI, Joe Mark and Mike Miller had to come up with some sort of solution. They couldn't use the electric motor that they had been using in their other devices. So the evidence will show that the solution they came up with was to use air motors instead of electric motors. Now, using air motors in minimally invasive tissue removal devices was not a new idea, but Suros was the first to use air motors in a minimally invasive device for use in breast biopsies. And this

new and unique idea is what made the ATEC lighter and faster and also compatible with MRI.

Now, is MRI important to doctors? Yes. During the trial you will hear from testimony from Dr. Michael Nelson. Dr. Nelson is a practicing physician who's performed thousands of breast biopsies. And he will tell you -- he will provide you with his opinions on the ATEC and its improved technology.

One of the things that Dr. Nelson will tell you is that while MRI biopsies do not represent the highest volume group of biopsies, MRI is the best imaging technology to be used in women at high risk of breast cancer. So to be able to do minimally invasive biopsies with MRI was a great advance for those women. And because of the innovations of Joe Mark and Mike Miller, those women now have an opportunity to have minimally invasive breast biopsy with MRI.

Now, five years after the ATEC came onto the market, Suros Surgical Systems was sold to Hologic. And you might wonder why would Joe Mark and Mike Miller sell their company when it was doing so well. It's because Hologic and Suros are a good match. Hologic is a women's health care company and a leading manufacturer of mammography equipment. So Hologic was already in the business of selling imaging devices for use in breast care and they also had a good working relationship with doctors and clinics around the country.

During the trial, you will hear from Hologic's

president and CEO, Mr. Robert Cascella. And Mr. Cascella will explain to you that Hologic purchased Suros because it had been distributing the ATEC since 2003 and believed that the Suros technology was the best available technology. So the acquisition made sense.

This also worked out well for Joe Mark and Mike Miller who retained rights to their basic MIS platform technology and can now turn to expanding that technology to other uses. They're now working on adapting the MIS platform for use in neurological applications.

So getting back to my three key points. On point number one, we believe the evidence at trial will show that the ATEC is the finest, most advanced breast biopsy device on the market and that it is based on tissue removal technology developed and patented by Joe Mark and Mike Miller before any of the Ethicon patents at issue in this case was ever filed.

Now I'd like to turn to point number two, what the evidence will show about the Ethicon patents being asserted in this case. In addition to the testimony you will hear from Joe Mark and Mike Miller about their work on minimally invasive tissue removal devices in the late 1980s and early 1990s, we will present testimony from two experts in the medical device field who will talk about what was publicly known about biopsy devices during the relevant time period. You will hear from Dr. David Lipson who holds a PhD in biomedical engineering and

who worked in the medical device industry for about 20 years. You will also hear from Mr. Michael Plishka, a mechanical engineer who has also worked in the medical device industry and who has actually designed devices for use in breast biopsies. What these experts will explain and what the evidence will show is that the Ethicon patents being asserted in this case are not inventive and are directed -- are directed to obvious combinations of basic elements that people working in the tissue removal field already knew about, tube in tube cutters, vacuum assistance, tissue filters, displays with icons.

The Ethicon patents, as Ms. Bresnick said, started with a company called Biopsys Medical, Inc. In March, 1994, Biopsys filed the patent application that eventually led to the '424 patent that Ethicon is asserting in this case. And I have a copy of the '424 patent here which Ms. Bresnick already explained a little bit to you.

This invention, the invention described in this patent, includes a lot of the same features that others in the field were already using before this patent was filed. For example, it covers a method for extracting a tissue sample from a patient. The patent requires the use of an instrument with a piercer, with an opening for receiving tissue, and a cutter that moves inside the piercer to cut tissue. The patent also discloses the use of vacuum power to draw tissue into the piercer. If all this sounds familiar, it should because we've

already talked about them in conjunction with the MIS device, the diskector, and Joe Mark's first patent on minimally invasive tissue removal that were done before the application that led to this patent was ever filed.

During this trial Hologic will not dispute that the early work Biopsys did on breast biopsy devices was important. The Mammotome was a good device for its time. But consoles, inner cutters, outer piercers, and the use of vacuum to remove tissue was not new and was well-known before this patent was filed.

Now, the evidence will show that Bi -- Ethicon bought Biopsys in 1997 and acquired the Biopsys Mammotome and the Biopsys patents, and one of the first things Ethicon did after that acquisition was start getting more and more patents on tissue removal devices. Now, Ethicon has suggested that it started making improvements to the Mammotome and the later patents cover those improvements, but the evidence and timeline will show a different story.

At this point you may be asking yourself if Joe Mark's MIS system and his own patent already covered these minimally -- had these features, how could the Patent Office have granted additional patents to Ethicon? The answer has a lot to do with how the U.S. patent system works. You heard in the video yesterday that an inventor can only patent something that is new and different. Sometimes this means a ground-

breaking invention that hasn't been done before like the example used in the video, it referred to Edison's light bulb, but other patents only cover improvements to existing technology. Just think about all the different light bulbs you have ever seen through the years. Some of those are probably patented because they reflect significant improvements to Edison's original invention or even just the light bulbs that came before them, but some aren't patented at all because they just don't represent improvements over what existed before.

Now, Ethicon has talked about the claims and the patents that it is accusing the ATEC of infringing. A patent claim if you -- and Ms. Bresnick highlighted the claims and showed what we didn't dispute. Now, a patent claim, if you recall from the video this morning, describes the invention and sets the boundaries of it. You might have a patent claim on improvement to a light bulb that covered a light bulb with a new type of filament. That -- the patent claim to that type of light bulb would include the special new type of filament but it would also include the old elements of a light bulb that were known in the prior art such as the glass light bulb, even though most of those other elements, everything except the new type of filament, were already out in the public domain. In other words, the claim would describe the whole light bulb even though the real invention is a light bulb with a very special type of filament.

But you can't patent something that's an obvious improvement. An improvement has to be inventive, something new, something different, something that people in the field wouldn't have thought about. In the patent video that you saw yesterday, the term used is "nonobvious." If nobody had thought to use that particular type of metal for a filament, it might be an invention. But if it was well-known that that type of metal could be used for a filament and it would be easy to do, then it couldn't -- it wouldn't be inventive and it wouldn't be entitled to a patent.

So before I get into the details of Ethicon's patents, I want to set forth what we believe the evidence will show about what Ethicon did not invent, what was already in the prior art or the public domain.

What the evidence will show is Ethicon did not invent minimally invasive tissue removal systems. Ethicon did not invent a tube in tube cutting system. Ethicon did not invent the use of vacuum in tissue removal systems. Ethicon didn't invent hand-held devices for minimally invasive tissue removal. Ethicon didn't invent tissue removal devices with a display panel. Ethicon didn't invent tissue containers for holding tissue in minimally invasive devices. All of these concepts were in the public domain before any of the patents Ethicon is asserting in this case were filed. The inventors of the ATEC had used all those elements in their own devices before the

earliest Ethicon patents were filed.

So do the Ethicon patents add anything new to what was already known about minimally invasive tissue removal devices? And I would like to start with the '424 patent.

Now, we've talked that the evidence will show that much of what is claimed in the '424 patent is not new. Outer hollow cannulas with an opening for receiving tissue, inner cutters weren't new. The use of vacuum power to draw tissue into the opening wasn't new. But the claims also require, and Ms. Bresnick touched upon this, that vacuum pull tissue from the cutter and deposit it in what is called the tissue sample holder, and this is indeed the focus of our dispute with Ethicon.

The evidence will show that tissue sample holders aren't anything new. Joe Mark and Mike Miller had made devices with containers that held tissue, the MIS, their basic platform technology, the diskector device, the vitrectomy device, and in fact, the Court has said that the invention in the '424 patent contemplates more than a mere tissue sample holder. So the tissue -- the Court has decided what the words "tissue sample holder" mean in the context of the patent. And I just want to put up the Court's definition. And in particular, it has to be a receptacle, cartridge, cassette or other tissue sample holder that is suitable.

Now, at one point Ms. Bresnick referred to being

capable of being used for housing tissue samples. Now, the Court's construction is "suitable for housing tissue samples during collection and transportation for analysis." This makes sense in the context of the patent. In particular, the patent described the use of a molded tissue cassette housing. And this was for -- this is the source of the construction for transportation for analysis. Now you will have to decide whether the ATEC has a tissue sample holder that falls within the Court's definition, i.e., "a tissue sample holder suitable for housing tissue samples during collection and transportation for analysis," and the evidence will show it does not.

Now, this is the component of the ATEC that Ethicon is accusing -- is calling a tissue sample holder (indicating). This is a mesh filter that traps tissue samples while allowing vacuum to pull liquid through the mesh filter. The tissue filter in the ATEC includes a small piece that's called a spatula. And the evidence will show the purpose of this spatula is so that once the biopsy procedure is completed, the doctor or nurse can remove the tissue from the filter with the spatula and put the samples into a container that is properly sealed for transportation for analysis.

Now, because it may be difficult to see the holes in this mesh, I want to show you how porous it is by pouring water through it. (Demonstrating.) So you can see the water flows right through that mesh filter. Liquid is also caught in the

mesh on the side of the filter. And you can see the top of the filter is open. We will ask -- yet Ethicon is claiming that this container is suitable for transporting tissue samples from the breast biopsy for analysis. We will ask that you use your common sense when you evaluate whether this is a container that's suitable for transporting tissue samples for analysis. Can you imagine any doctor in this day and age with high levels of concern over infectious disease and the like transporting tissue samples in this mesh container?

Now, Ms. Bresnick also said this container is suitable for housing tissue samples for analysis because it could be placed in another jar and taken to a laboratory. And I would ask you is a bicycle suitable for crossing the river if you have to put it on a ferry and cross the river that way? Of course not.

Now I want to talk about the '487 and '768 patents. The evidence will show that these patents just do not rise to level of improvements on the prior art that warrant a patent. They represent obvious, insignificant changes to the original work done at Biopsys with the Mammotome. The patent application that resulted in the '487 and '768 patents was filed in December, 1999. To orient you in the chronology, that is six years after Joe Mark and Mike Miller had started selling their diskector and more than five years after Biopsys filed its original patent on the Mammotome.

Now, here's a picture of the display on the Mammotome. The evidence will show that there are only two differences between what Ethicon is claiming is inventions in the two display patents, '487 and the '768 patents, and this device. First, those patents disclose the use of icons or pictures to describe operational modes, so pictures instead of words. That's one supposed innovation. Secondly, they disclose the use of a control button instead of a control knob. So what the Ethicon engineers did was take the Mammotome, modify the display panel to use pictures instead of words, icons, and control buttons instead of a control knob and then they filed a patent on that.

One of the issues we will ask you to decide is whether you think that is an invention that entitles Ethicon to a patent. The evidence will show it is not. The use of icons on medical devices is nothing new. Take a look at Joe Mark and Mike Miller's diskector which was sold in 1993, six years before these Ethicon patents were filed. Here on the console of the diskector is a display with icons. There's a picture of a hand holding a handpiece, a foot on a foot pedal. Use your common sense and experience. Using icons isn't -- on a medical device is not inventive. People in the field had been doing this for years. Same with control buttons instead of control knobs. These just aren't new ideas.

And Ethicon is not only claiming it's entitled to a

patent on these inventions, it's going a lot further than that. You heard Ms. Bresnick, Ethicon is also claiming it's entitled to damages of 92 million dollars for these inventions. And I want to show you to avoid the '768 and '487 patents, here's all Suros would have to do. This is the current display panel on our device (indicating). All we would have to do is cover up those icons and we would not have the icons that are claimed in the '768 and '487 patents. It would still -- the device would still be compatible with MRI, we'd still have our lighter handpiece, it would still allow doctors to perform the exact same procedures. The only difference would be no icons. Is that worth 92 million dollars?

The ATEC includes many important innovations that were the product of hard work by Joe Mark, Mike Miller, and others. The evidence will show that the patents Ethicon is asserting here are not innovative and are obvious and do not entitle Ethicon to damages.

Now I'd like to move on to my point number three which goes to why I think we're all here and more specifically why this litigation was filed in 2007 even though the ATEC has been on the market for much longer than that.

As we've discussed, the evidence will show that Biopsys created a minimally invasive vacuum-assisted tissue removal device adapted to breast biopsy using well-known and well-established technology. We aren't here to criticize the

Mammotome. The Mammotome improved the diagnosis of breast cancer, and when it was first introduced in the mid 1990s, it was a good device for its time. The reason we're here is what happened after that. The evidence will show that when Ethicon purchased Biopsys, it began selling a new device in a market with no competitors. They came up with ideas for minor changes to the Biopsys device such as adding some icons, swapping a knob for a button on the display panel, and they filed patents on those little improvements one right after another.

Then the next generation device came along. The evidence will show it was another small company, Suros, that raised the bar by developing an innovative device. Ethicon watched ATEC closely, and the two competed in the market. For example, the evidence will show Ethicon started selling the Mammotome hand-held device for ultrasound in 1999 before the ATEC was on the market. In January, 2002, Suros launched its ultrasound ATEC device which because of the air motor was half the weight of the Mammotome HH. So what did Ethicon do? It developed its own lighter device and stopped promoting the Mammotome HH.

In 2003, Suros came out with MRI-compatible ATEC device. That was a goal that Joe Mark and Mike Miller had set for themselves very early on. In 2003, there was no Mammotome that could be used with MRI. So what did Ethicon do? Ethicon developed its own MRI-compatible device and launched that

product two years later in 2006.

So what you had was two companies competing to develop better technology to the benefit of everyone. In all this time did Ethicon file a lawsuit? No. Does Ethicon write a letter mentioning these three patents? No. No. The ATEC went on the market in January, 2002. The evidence will show Ethicon didn't file suit in 2002, in 2003, in 2004, in 2005, in -- or even in 2006. But when Hologic bought Suros, everything changed. After the acquisition, you no longer had a tiny company competing against Ethicon. Sales of ATEC handpieces increased dramatically. And I have a chart here that can show you what happened. So here's the launch of the ATEC, and this is the point at which Hologic acquired Suros. All of a sudden after years without saying anything, Ethicon sues Hologic and Suros for patent infringement. Does that sound right?

The evidence will show this is a story not of one company using another company's technology, the story Ethicon would like you to believe. The evidence will show that one company who was not competing in the marketplace with technology resorted to allegations of patent infringement instead.

Ethicon wants you to give them credit for inventing vacuum-assisted tissue removal technology, but the evidence will show they did not do that. Vacuum-assisted tissue removal technology was already in the public domain. What they did was

purchase a first generation device in a market with no competition and they made a lot of money doing it. Once the next generation device, ATEC backed by Hologic, started eating into their revenues, they filed this lawsuit.

The evidence will show that what Joe Mark and Mike Miller did was important. They worked hard. They improved technology women need for better diagnosis of cancer. The ATEC is a product of their hard work, their innovation, their good ideas. At the conclusion of the evidence, we will ask -- come back and ask you to return a verdict in favor of Hologic.

We look forward to presenting our case to you and thank you again for your attention.

THE COURT: All right. Thank you, counsel.

Ladies and gentlemen, I think we'll take our morning recess now for a couple of reasons. One, Julie is here. Julie is here now and she's going to switch off with Maryann. I introduced Maryann to you yesterday but this is Julie, and she and Maryann are going to switch off during the course of the trial.

And when we come back, we'll have our first witness.

Now, just a couple things about the break. If I forget to say this at any time you guys go out of the room, the same instruction applies.

You're not to form or express any opinion about the case until the very end of the case because until you've got

the instructions of law, you're not quite sure what all the facts mean, okay. If you express a opinion to somebody, it may cause a problem. All right. Obviously in your own mind you're thinking about the case, but keep it in your own mind. Don't talk to anybody else about it. All right.

And, again, no type of independent research, experiments, or anything like that. Don't reach out to anybody for any questions about this. As we pointed out, these kinds of medical issues touch a lot of people. Don't be tempted to talk to somebody that might be a friend of yours that's had some type of procedure and ask them about it or anything like that, okay.

So let common sense sort of dictate how you keep your lips zipped, okay.

Now, the other thing is generally we like you guys to sort of hang together. I think there's enough facilities back here to accommodate everybody, but I also understand that people like me who have a bad back sometimes need to get up and walk around, somebody might want to go outside and take a smoke. So if you're doing something like that, do it, but just be back in the box by the time we're ready to start, okay.

So why don't we make this break fifteen minutes. That will give counsel a chance to set up whatever they need to set up for the first witness.

So don't form or express any opinions about the case.

Generally try to stick together back there. If you need to, you know, get some, catch some fresh air -- do they have to go outside to smoke or is there a room upstairs?

COURTROOM DEPUTY: There's a room upstairs.

THE COURT: So it's your preference. I don't know if we have any smokers in the crowd, but there's a room upstairs and you can also go outside, okay.

And, again, what I said yesterday, there's a lot of participants involved in this and a lot of lawyers. Nobody is going to think you're rude or impolite if you don't talk to them. In fact, you're not supposed to talk to them and they're not supposed to talk to you. Fair enough?

Okay, guys, why don't we just make it quarter of on our clock. Fair enough?

Thanks. We'll stand in recess.

(Jury out at 10:28 a.m.)

THE COURT: Yes, sir.

MR. ZEGGER: Your Honor, out of politeness to opposing counsel we didn't object during their opening statement, but we strenuously renew our objection that I made yesterday regarding the content of this opening.

What we heard this morning --

THE COURT: You guys can sit down.

MR. ZEGGER: What we heard this morning, Your Honor, was that this earlier work with the diskector and the '276

patent of Mark and Miller invalidates our patents. That is an argument that we have not seen in any pleading, we have not seen in any invalidity contentions. It's not in any expert reports. I've been working on this case for over two years, and this is the first time that we've seen that argument.

Now, we can't unring the bell, but we strongly believe that there should be some curative instruction to the jury that defendants are not relying upon the diskector and the '276 patent to invalidate.

If they want to argue that this shows a development story, fine, but it's not an invalidity argument.

THE COURT: Who is going to handle that?

MS. PIROZZOLO: Your Honor, the '276 patent is on our 282 notice and it is in our expert reports. And the other devices are part of our inventory. They're where the ATEC product came from, and that was the context I referred to them.

MR. ZEGGER: The '276 patent is not in any combination offered by any witness, and I think we've just heard a denial that there's any invalidity story based on the diskector.

THE COURT: Who's going to testify to it? Is there an expert that's going to testify to invalidity based upon --

MS. PIROZZOLO: The '276 patent was referenced in Mr. Michael Plishka's expert report and Dr. David Lipson's report, and they will be referring to that patent during their testimony. And Mr. Mark and Mr. Miller will be testifying

about their early work with the diskector and the MIS platform device which we had disclosed in discovery as where they got the ideas for the ATEC product.

THE COURT: I mean, is it in the reports or not, counsel?

MR. ZEGGER: The '276 patent is listed in the report. It's one of dozens and dozens of references, but it's not in any specific combination to invalidate. And I think we heard again that the diskector is not being relied upon for invalidity. That should be made clear to the jury because what I heard this morning was that the early diskector work was prior to our patent filing and could invalidate the patents. That's not in any report. And if it's only being relied upon to show development of the ATEC, fine, but not for invalidity.

MS. PIROZZOLO: Well, the '276 patent, there is a paragraph in the experts' expert reports and they will be testifying about that. It's prior art, and we're asserting that these patents are obvious in what was known -- in light of what was known to people of ordinary skill in this field at the time. So we are relying on the '276 patent and we think we're entitled to rely on what the inventors of our accused product was doing before the patents in this case were filed.

THE COURT: Okay. The objection is overruled. As we start getting into the evidence, you can renew your objections. All right.

All right. Guys, I'll see you in about fifteen minutes.

MR. GUNTHER: Thank you, Your Honor.

(Recess in proceedings at 10:32 a.m.)

- - -

C E R T I F I C A T E

I, Julie A. Wolfer, the undersigned, do hereby certify that the foregoing is a correct transcript from the record of the proceedings in the above-entitled matter.

s/Julie A. Wolfer
Julie A. Wolfer, RDR, CRR
Official Reporter